

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Michael Bardroff et al. Art Unit : 1649
Serial No. : 10/505,313 Examiner : Gregory S. Emch
Filed : March 7, 2005 Conf. No. : 1924
Title : ANTI-AMYLOID BETA ANTIBODIES

Mail Stop Petitions

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.181(a)(3)
TO INVOKE THE SUPERVISORY AUTHORITY OF THE DIRECTOR

Applicants hereby petition under 37 C.F.R. § 1.181(a)(3) to invoke the supervisory authority of the Director in response to a Decision on Application for Patent Term Adjustment (“the Decision”) mailed by the Office of Petitions on June 22, 2010.

The Decision adjusted the Patent Term Adjustment (PTA) at the time of the mailing of the Notice of Allowance for the present application to 15 days. Applicants contest the PTA calculation made by the Decision, as well as a procedural irregularity raised by the Decision, and request that the PTA at the time of the mailing of the Notice of Allowance be modified to 291 days.

I. The Decision Applies a New PTA Reduction Yet Does not Provide Applicants a Period to Reply and Request Reconsideration

A Notice of Allowance was mailed for the application on August 21, 2009, stating that the application is entitled to 95 days of PTA. Applicants filed a Request for Reconsideration of PTA on October 16, 2009, requesting that the application be accorded 291 days of PTA. The Decision rejected applicants’ request and also raised a new allegation that an additional circumstance (never raised previously by the Office) during prosecution constituted a failure to engage in reasonable efforts to conclude processing or examination of the application (see Section II below for a detailed rebuttal of the Office’s position on this new issue). In view of this newly raised issue, the Decision concluded that the PTA at the time of the mailing of the

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Notice of Allowance should have been 15 days. The Decision provided no period for applicants to file a reply to request reconsideration of this new PTA reduction.

Applicants request the intervention of the Director to address the fundamental unfairness that results from the Decision's failure to provide applicants an opportunity to respond to a reduction of PTA based upon a prosecution event that had never been alleged previously to be a trigger for PTA loss. It is unclear where in the statute or regulations the Office derives the authority to raise at this late juncture (i.e., in a Decision in response to applicants' submission on another PTA matter) a new issue causing a further reduction in PTA. Notwithstanding the procedural irregularity, the raising of a new issue without providing a mechanism for applicants to reply and have the matter reconsidered is manifestly unfair. Applicants request the Director's intervention to ensure that the detailed request in Section II below is reviewed carefully with the understanding that this is the first opportunity applicants have had to address this issue. Applicants also request that the Director ensure that the filing of the present petition not be treated as a basis for applicant delay, since it was the Office's raising of this new issue in a time and manner not provided by the statute or regulations that resulted in the necessity of filing the petition.

II. Applicants' Response Filed on July 27, 2007 was Compliant and Should Not Trigger Applicant Delay

As noted in Section I above, the reduction of PTA under this heading was raised by the Office for the first time in the Decision dated June 22, 2010. As a result, this petition is the first opportunity applicants have had to respond to this new issue.

In response to a Restriction Requirement dated June 5, 2007, applicants filed a response on July 27, 2007. A Notice of Non-Compliant Amendment was mailed on October 18, 2007, and a response thereto was filed on October 25, 2007.

The Office has charged applicant delay under 37 C.F.R. 1.704(c)(7) for a period of 90 days, beginning on July 28, 2007 (the day after the date the reply to the Restriction Requirement was filed), and ending on October 25, 2007 (the date that a reply to the Notice of Non-Compliant Amendment was filed). Assessment of applicant delay would be appropriate only if the response filed on July 27, 2007 was non-compliant. However, for the reasons detailed

below, the response filed on July 27, 2007 was fully compliant and the Notice of Non-Compliant Amendment mailed on October 18, 2007 was improper.

The Restriction Requirement divided the claims into four groups and three species. In the response filed on July 27, 2007, applicants elected a single group and a single species. The response included a claim amendment, wherein those claims directed to non-elected subject matter were identified with the status identifier "withdrawn." In the Notice of Non-Compliant Amendment, the Examiner stated that it was improper to have used the status identifier "withdrawn" because "[c]laims are withdrawn from further consideration by the Examiner" and "the Examiner has not withdrawn any of the claims." See Continuation Sheet of Notice of Non-Compliant Amendment dated October 18, 2007. In the response filed on October 25, 2007, applicants explained that the use of the "withdrawn" status identifier was based on the Examiner's restriction requirement (i.e., claims corresponding to non-elected subject matter had been listed as "withdrawn"). However, applicants rendered the issue moot simply by cancelling the previously "withdrawn" claims in the response filed on October 25, 2007.

In the Notice of Non-Compliant Amendment, the Examiner cited 37 C.F.R. 1.142(b) in support of the assertion that applicants were wrong to have used the status identifier "withdrawn" to refer to non-elected claims. However, applicants' use of the "withdrawn" status identifier was not only compliant but was in fact mandated by the same regulation cited by the Examiner. "Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled." 37 C.F.R. 1.142(b) (emphasis added). In addition, the Manual of Patent Examining Procedure (MPEP) instructs that "[f]or any amendment being filed in response to a restriction or election of species requirement and any subsequent amendment, any claims which are non-elected must have the status identifier (withdrawn)." MPEP 714 (emphasis added).

In view of the unambiguous instructions provided by both 37 C.F.R. 1.142(b) and MPEP 714, applicants were correct to identify as "withdrawn" those claims that were neither cancelled nor directed to the elected invention. In fact, it would have been non-compliant for applicants to have used a status identifier that did not include the term "withdrawn" for the non-elected claims. No further confirmation of the Restriction Requirement or other intervention by

the Examiner was required to cause the withdrawal of the claims. As a result, the response to Restriction Requirement filed on July 27, 2007 was compliant and the Examiner's assertion to the contrary in the subsequent Notice of Non-Compliant Amendment was in error.

In view of the fact that the response filed on July 27, 2007 was compliant, applicants should not have been assessed applicant delay under 37 C.F.R. 1.704(c)(7) for the 90 day period beginning on July 28, 2007, and ending on October 25, 2007.

III. Applicants' Responses Filed on July 2, 2008 and July 28, 2008 were Compliant and Should Not Trigger Applicant Delay

As an initial matter, applicants do not understand the assertion in the Decision that by contesting the propriety of the Office's PTA reduction associated with the responses of July 2, 2008 and July 28, 2008, "Applicants essentially seek to reopen prosecution after prosecution has been closed." Applicants' request for reconsideration of PTA in no way sought to reopen prosecution. Rather, applicants requested that the Office of Petitions apply the PTA statute and regulations to the facts in this application, which necessarily requires a consideration of whether the responses contained an "omission" and should be the basis of applicant delay under 37 C.F.R. 1.704(c)(7). For the following reasons, it can easily be understood that the responses filed on July 2, 2008 and July 28, 2008 did not contain an omission and that this fact was confirmed by the Examiner during prosecution.

Applicants filed a response to Office Action on July 2, 2008. Subsequently, applicants filed a supplemental response requested by the Examiner on July 28, 2008.¹ A Notice of Non-Responsive Amendment was mailed on October 14, 2008, and a response thereto was filed on January 16, 2009.

The Office has charged applicant delay for a period of 198 days, beginning on July 3, 2008 (the day after the date the initial reply to Office Action was filed) and ending on January 16, 2009 (the date that a reply to the Notice of Non-Responsive Amendment was filed).

¹ The supplemental response was requested by the Examiner and therefore does not result in applicant delay under 37 CFR 1.704(c)(8) from July 3 to 28, 2008. The Office has made no allegation that the filing of a supplemental response should be the basis of any of the applicant delay charged in the Decision. Instead, the Decision refers only to periods of alleged delay resulting from filing a reply having an "omission" and the subsequent filing of a paper correcting the alleged omission (which necessarily invokes 37 CFR 1.704(c)(7)).

Assessment of the applicant delay would be appropriate only if the responses filed on July 2, 2008 and July 28, 2008 were non-responsive. However, for the reasons detailed below, the responses filed on July 2, 2008 and July 28, 2008 were fully compliant and the notice of Notice of Non-Responsive Amendment mailed on October 14, 2008 was improper.

The Notice of Non-Responsive Amendment asserted that “[t]he amendment filed on 28 July 2008 canceling all claimed subject matter drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive.” The Notice of Non-Responsive Amendment also asserted that the amendment filed on July 2, 2008 contained only claims to a non-elected invention and was therefore non-responsive. During subsequent prosecution, applicants successfully contested the assertion that the amendments of July 2, 2008 and July 28, 2008 were non-compliant, as follows.

- On December 3, 2008, applicants conducted an interview with the Examiner to explain why the amendments of July 2, 2008 and July 28, 2008 were directed to the elected invention and therefore not non-responsive. The Examiner requested applicants to memorialize the remarks presented in the interview in a written response (which response was filed on January 16, 2009).
- On January 16, 2009, applicants filed a response that presented the detailed reasoning of why the amendments of July 2, 2008 and July 28, 2008 were directed to the elected invention and therefore not non-responsive. Applicants did not amend the claims in this response.
- On April 29, 2009, the Examiner issued a final office action, allowing some claims and rejecting others. The Office Action reviewed in detail the amendments of July 2, 2008 and July 28, 2008 and stated (at page 3) that “Applicants’ arguments have been fully considered and are found persuasive. The examiner agrees that claim 1 and dependent claims still encompass the elected antibody of MSR-7.” (emphasis added).

The facts summarized above establish unequivocally that the responses of July 2, 2008 and July 28, 2008 were not non-responsive. This conclusion is reached without difficulty by observing that: (1) applicants response of January 16, 2009 contesting the Notice’s assertion that

the claim amendments were non-responsive contained argument only (i.e., the claims were not further amended); (2) subsequent to applicants' response of January 16, 2009, the Examiner continued with examination of the claims in the next Office Action (of April 29, 2009), which continued examination would have occurred only if the Examiner no longer considered the amendment to have been non-responsive; and (3) the Examiner explicitly stated in the next Office Action (of April 29, 2009) that applicants' arguments rebutting the asserted non-compliance of the amendments of July 2, 2008 and July 28, 2008 were persuasive. These facts constitute clear and convincing evidence that the responses of July 2, 2008 and July 28, 2008 were proper and that the Office's subsequent Notice of Non-Responsive Amendment was in error.

There is no reasonable basis for the Decision to have reached a result other than the one summarized above. The Decision appears to suggest that in order for applicants to have avoided facing a PTA penalty under 37 C.F.R. 1.704(c)(7), they should have filed a Petition under 37 C.F.R. 1.181 to have had this issue reviewed during prosecution. Applicants find no support in the PTA statute or regulations for this suggestion and request that the Director evaluate whether the responses of July 2, 2008 and July 28, 2008 were non-responsive. As summarized above, applicants resolved this issue during prosecution by convincing the Examiner (who was familiar with the complicated subject matter) in an interview and a written response. The conclusion that the responses were proper is therefore easily reached.

In view of the fact that the responses filed on July 2, 2008 and July 28, 2008 were responsive, applicants should not have been assessed applicant delay under 37 C.F.R. 1.704(c)(7) for the 198 day period beginning on July 3, 2008, and ending on January 16, 2009.

IV. Conclusion

The Decision modified the PTA at the time of the mailing of the Notice of Allowance for the application to 15 days. For the reasons detailed herein, the two periods of applicant delay assessed under 37 C.F.R. 1.704(c)(7) are improper and should be removed. As a result, and on the basis of the calculation presented in the request for reconsideration of PTA filed on October 16, 2009, the total PTA for the application at the time of the mailing of the Notice of Allowance should be modified to 291 days.

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Please apply any charges or credits to Deposit Account No. 06-1050, referencing
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Respectfully submitted,

Date: August 20, 2010

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